

Claims

What is claimed is:

- 5 1. A substrate coating for the electrostatic deposition
of dry powder medicaments for use in the manufacture
of pharmaceutical dosage forms comprising micronized
polyethylene glycol (PEG), with molecular weight in
the range of 1,000 to 20,000, and having a particle
size of 1- 100 μm .
- 10 2. The substrate coating of claim 1 having a melting
point in the range of 50 - 63°C.
- 15 3. The substrate coating of claim 1 wherein the PEG has
a molecular weight in the range of 6,000 - 8,000.
- 20 4. The substrate coating of claim 1 also containing a
plasticizer.
- 25 5. The substrate coating of claim 4 wherein the
plasticizer is selected from castor oil, polyethylene
glycol, propylene glycol or glycerine.
6. The substrate coating of claim 1 also containing one
or more coloring, pacifying, flavoring and/or
sweetening agents.

7. A pharmaceutical composition comprising an edible substrate having micronized drug substance with a particle size of 1 - 100 μm deposited on the surface of the substrate by electrostatic dry powder deposition, and a film coating on the substrate and drug substance consisting essentially of micronized polyethylene glycol (PEG), with molecular weight in the range of 1,000 to 20,000, and having a particle size of 1- 100 μm .
8. The pharmaceutical composition of claim 7 wherein the film coating has a melting point in the range of 50 - 63°C.
9. The pharmaceutical composition of claim 7 wherein the PEG has a molecular weight in the range of 6,000 - 8,000.
10. The pharmaceutical composition of claim 7 wherein the PEG film coating (dried) constitutes from about 1 to about 10, percent by weight of the total weight of the solid dosage form.
11. The pharmaceutical composition of claim 7 wherein the edible substrate is comprised of a tablet core.
12. The pharmaceutical composition of claim 8 wherein the tablet core is prepared by compressing a mixture of microcrystalline cellulose (99 - 99.5%) and magnesium stearate (0.5 - 1%).
13. The pharmaceutical composition of claim 7 wherein the drug substance is selected from one or more estrogens and/or progestins.

14. The pharmaceutical composition of claim 13 wherein
the drug substance is a combination of norgestimate
and ethinyl estradiol.
- 5
15. In a process for manufacturing pharmaceutical unit
dosage forms by the electrostatic deposition of dry
powder medicament to a substrate, the improvement
comprising coating the substrate in place with dry
10 micronized polyethylene glycol (PEG), melting the
dry polyethylene glycol coating and allowing it to
cool whereupon a protective coating is formed.
16. A method of depositing negatively charged dry powder
medicament on a negatively charged substrate by an
electrostatic dry powder deposition process, the
method comprising reversing the charge of the
medicament to a positive charge by mixing the
negatively charged medicament with micronized
20 polyethylene glycol (PEG), at the ratio of
medicament to PEG of 1:1 to 1:60, and then
depositing the mixture onto the negatively charged
substrate.
- 25 17. The method according to claim 16 wherein the PEG has
a molecular weight in the range of 1,000 to 20,000
and a particle size of 1-100 μm .
18. The method according to claim 16 wherein the PEG has
30 a melting point in the range of 50-63°C.
19. The method according to claim 16 wherein the PEG has
a molecular weight in the range of 6,000 to 8,000.

Add
A:7